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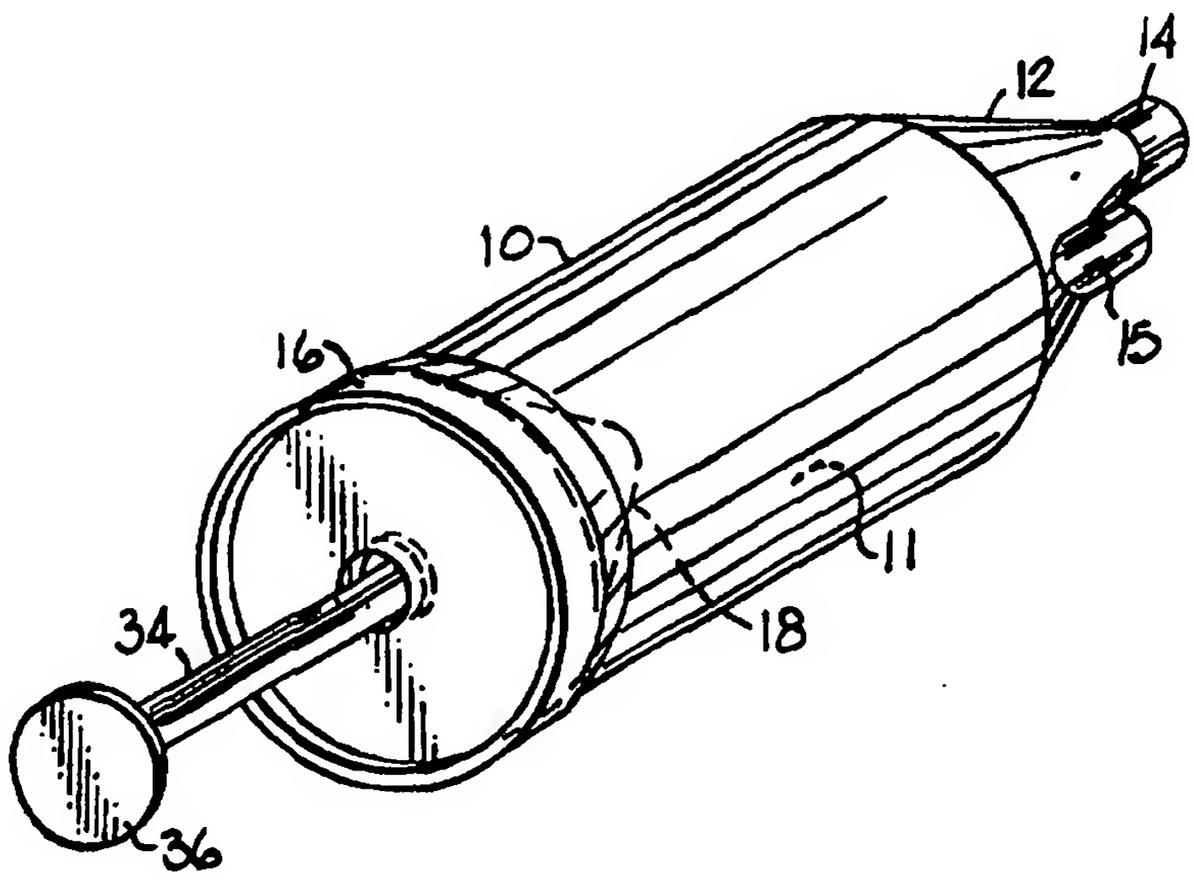

(57) Abstract

A medicinal syringe includes a plunger (16) with a non-integral plunger stick (30), and the plunger is completely contained within the syringe barrel (11). A plunger stick (30) may be detachably attached to the plunger (16) for transporting fluid into and out of the syringe. The syringe is further adapted for use with a pumping mechanism (40) having an integral plunger. The pumping mechanism (40) may positively connect with the plunger (16) to prevent inadvertent plunger motion and consequent loss of medicine. The syringe may be partially or completely hermetically sealed by applying a membrane (270) across its distal end to insure sterility.

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MEDICAL SYRINGE

FIELD OF THE INVENTION

The present invention relates to the field of medical infusion devices such as syringes and syringe pumps, and more particularly to a syringe having a removable plunger stick, that may be driven by a pump with an integrated plunger stick, and that may be hermetically or partially hermetically sealed.

BACKGROUND OF THE INVENTION

Syringes are commonly used for the delivery of fluid medication into the body of a patient. Traditional syringe design includes a hollow barrel having a fluid port on one end to dispense the medication into the patient, either directly, or, more commonly, indirectly such as through a needle or catheter. The end of the syringe barrel having this fluid port shall be termed the "proximal" end, and thereby define the proximal and distal directions used herein.

The medication is expelled from the syringe by a plunger slidably located within the syringe barrel. The plunger occupies the cross section of the barrel with a close tolerance, to form a fluid and gaseous-tight seal therewith. The syringe is filled by first advancing the plunger towards the proximal end of the barrel, thus expelling the barrel of air. The fluid port is then placed in fluid communication with a reservoir of medicine, and the plunger is withdrawn, creating vacuum pressure to fill the barrel.

The medication is introduced into the body of a patient in essentially the reverse process, such as by placing the proximal port in fluid communication with a needle or catheter inserted into the patient, and driving the plunger towards the fluid port to force the medicine

therethrough. The rate of medicine delivery may be controlled by using a motorized or other type of pump to drive the plunger through the syringe barrel. Delivery rate is important for optimal therapeutic benefit; for example, if the rate is too slow, the medicine may not be fully effective, and if the rate is too fast, the medicine may have unwanted side effects or toxicity.

The conventional method of linking the plunger with the pump motor is by a plunger stick, that extends distally away from the plunger. The plunger stick is integrated with the plunger, and forms part of a generally disposable syringe package. The plunger stick, and the rest of the syringe, is typically discarded after a single use. In contrast to the prior art, the present invention does not have a permanently attached plunger stick. Instead, the plunger stick is integrated into the pump mechanism, so as to reduce the amount of material, and the cost, of a disposable syringe. However, it is still be possible to drive the plunger without the pump mechanism, for filling the syringe and for emergency purposes when the pump mechanism is unavailable. An alternate embodiment of the present invention does not require a plunger stick at all and is particularly suited for delivering medicine when precise control is not required.

Another difficulty raised by syringe plungers is the tendency of the plunger of a filled syringe to move towards the fluid port, because of gravity or perhaps other forces, before it is desired to expel medicine from the syringe. Preventing such motion is necessary to prevent accidental delivery of medicine and the waste of medicine, and to insure that the syringe will contain the desired amount of medicine when it is ready to be used. Known methods of preventing inadvertent plunger release involve securing a plunger stick attached to plunger.

However, such methods cannot be used with a plunger lacking an integrated plunger stick. Accordingly, another aspect of the plunger of the present invention is the ability to lock a plunger in place without having to make use of an integrated plunger stick.

Another problem related to therapeutic syringes is maintaining the sterility of the medicine after it is placed within a syringe. Desirably, the medicine could be prefilled within a syringe at a manufacturing plant, a pharmacy, or elsewhere for a substantial time before its intended use, and be maintained in a sterile condition until it is used. Accordingly, the present invention provides for a hermetic, or partially hermetic, seal across a syringe barrel, that is compatible with the plunger.

SUMMARY OF THE INVENTION

The present invention provides a syringe system useful to introduce medicine into the body of a patient. The invention includes a syringe barrel having a fluid port and plunger that slides within the barrel to expel medicine from the fluid port. The plunger does not include an integrated plunger stick. The plunger may be slid through the barrel by attaching a detachable plunger stick to the plunger, and manipulating the plunger stick. Alternatively, the plunger may be slid by engaging the syringe barrel to a pumping mechanism including a plunger stick, and activating the pumping mechanism.

The pumping mechanism allows for highly controlled motion of the plunger, to provide an optimally safe and effective drug delivery rate. The detachable plunger stick allows for filling the syringe barrel, and for emergency medicine delivery should the pumping mechanism be unavailable. Additionally, the construction of a plunger without an integrated pump stick saves on

material waste, as syringe barrels and plungers are typically disposable items. The detachable plunger stick and pumping mechanism, in contrast, may be used with an unlimited number of syringe barrels.

The invention further provides for positive locking between the pumping mechanism and the plunger. This prevents the plunger from inadvertently sliding within the barrel, and thereby inadvertently releasing medicine.

An additional improvement is a micro-organism barrier membrane that may be fitted over the syringe barrel, thereby insuring sterility until the medicine is delivered to the patient. The barrier may be fitted over the barrel either before or after the barrel has been filled. The membrane may be breathable or non-breathable, depending on the material selection, for various applications. A breathable barrier membrane would allow the pharmacist to fill the syringe using aseptic techniques and maintain the sterility of the container.

BRIEF DESCRIPTION OF THE DRAWINGS

In all of the drawings, interior portions are shown in phantom.

FIG. 1 is a perspective view of a syringe according to the present invention.

FIG. 2 is a perspective view of a detachable plunger stick according to the present invention.

FIG. 3 is a perspective view of the detachable plunger stick engaged with the syringe according to the present invention.

FIG. 4 is a perspective view of a pump mechanism according to the present invention.

FIG. 5 is a perspective view of the pump mechanism engaged with the syringe, according to the present invention.

FIG. 6 is view similar to FIG. 5 of the pump mechanism engaged with the syringe, with the plunger driven to release fluid.

FIG. 7 is a perspective view of a syringe and pumping mechanism according to the present invention with a positive locking means therebetween.

FIG. 8 is a perspective view of a syringe according to the present invention with a removable sterile barrier attached thereto.

FIG. 9 is a perspective view of a syringe according to the present invention with a removable sterile barrier, partially removed from the syringe.

FIG. 10 is an sectional view of an embodiment of the invention having a cap to attache the sterile barrier.

FIGS. 11 and 12 are elevation views of an embodiment of the invention having a gravity activated plunger.

DETAILED DESCRIPTION OF THE INVENTION

With reference to FIG. 1, the present invention includes a syringe barrel 10, that defines a bore 11 within the barrel. The barrel 10 has a fluid port 14 at one end, termed the proximal end herein, through which fluid may be introduced into or expelled from the bore 11. The barrel 10 preferably has a tapered cross section 12 proximate the fluid port 14, although this is not necessary. The barrel may also have a fill port 15, preferably also at the proximal end of the barrel 10, as an alternative means of introducing fluid into the bore 11.

A plunger 16 is slidably disposed within the barrel 10, and forms a close tolerance therewith to obtain a fluid and gaseous-tight seal between the plunger 16 and the barrel 10. The plunger 16 is preferably tapered at its

proximal end 18 to fit into the tapered region 12 of the barrel 10, although this is not necessary provided that there is an adequate interference fit between the plunger 16 and barrel 10.

With reference to FIGS. 2 and 3, a detachable plunger stick 30 may be detachably attached to the plunger 16. The plunger stick 30 includes a rigid, elongate member 34 that may be used to drive the plunger proximally and distally through the syringe barrel 10. The plunger stick 30 may attach to the plunger 16 by threads 32 on the proximal end of the stick 30 and a correspondingly threaded receptacle 20 in plunger 16. Alternatively, other mating means, such as adhesives or interference-fit means may be used. The plunger stick 30 preferably includes a handle 36 at its extreme distal end, that allows a user to conveniently attach the plunger stick 30 to the plunger 16 and thereafter to slide the plunger through the bore 11.

With reference to FIG. 4, a pump mechanism 40 is provided to drive plunger 16 independently of the removable plunger stick 30. The pump mechanism 40 allows for medicine to be delivered over a controlled period of time for maximum therapeutic benefit. A pump plunger stick 42 is slidably mounted within the pump mechanism 40. It should be understood that what is described as a "stick" is not necessarily limited to the pictured stick 42, but could be any structural member having the same function. A "stick" is believed to be the simplest and most effective shape, but the invention is no so limited.

The pump plunger 42 may be advanced or retracted through the mechanism 40. A pump motor 44, illustrated schematically, allows controlled motion of the pump plunger 42.

With reference to FIG. 5, the syringe barrel 10 is engagable with the pump mechanism 40. The pumping

mechanism may have a raised ridge 46 over which the barrel 10 may be press fitted; alternatively, other engaging means between the syringe barrel and the pump mechanism may be used. The engagement causes contact between the proximal end of the pump plunger stick 42 and the syringe plunger 16.

With reference to FIG. 6, after the barrel 10 is engaged with the pump mechanism 40, the pump plunger stick 42 may be driven towards the fluid port 14, in turn driving the plunger 16 towards the fluid port 14 and thereby delivering medicine from the bore 11 through the port 14. The rate of fluid delivery is set by the speed at which the pump motor 44 is operated.

In operation, the bore 11 is filled with a desired amount of medicine. This may be accomplished by attaching the detachable plunger stick 30 to the plunger 16, and advancing the plunger stick towards the proximal end of the bore 11 until the plunger 16 reaches the proximal section 12 of the syringe barrel. The fluid port 14 is then placed in fluid communication with a supply of medicine, and the plunger stick 30 is withdrawn towards the distal end of the bore 11. Vacuum pressure causes medicine to enter the bore 11 through the fluid port 14. The plunger stick 30 is withdrawn, until a desired amount of medicine occupies the bore 11.

Alternatively, medicine may be introduced into the bore 11 through a fill port 15 located at the proximal portion of the syringe barrel, without the use of a plunger stick. The medicine may be directly injected into the fill port 15, while the fluid port 14 is left open as a vent so that the medicine may be non-turbulently introduced. Of course, the medicine could be introduced into the fluid port 14, with the fill port 15 used as a vent--in either situation, the extra port in the proximal end of the barrel 10, if present, provides for more

filling options. It should be appreciated that both ports 14 and 15 may also be capped with plugs whenever necessary to seal the proximal end of the syringe barrel.

The detachable plunger stick 30 may be detached from the plunger 16 before the medicine is delivered to a patient. The syringe barrel 10 is engaged with the pump mechanism 40 prior to delivery, so that the plump plunger stick 42 contacts the plunger 16. The fluid port 14 is placed in fluid communication with the body of the patient, through suitable means such as a catheter or needle. The pump motor 44 then drives the pump plunger stick 42, and hence the plunger 16, towards the fluid port 14, and medicine is delivered to the patient.

Alternatively, medicine may be manually delivered to the patient by using the detachable plunger stick 30 instead of the pumping mechanism 40. Instead of detaching the plunger stick 30, the plunger stick may be driven towards the fluid port 14 to deliver medicine. If the plunger stick 30 has been previously detached, it may be reattached. This use of the detachable plunger stick 30 does not provide the same measure of control as does the pumping mechanism 40, but is available in emergencies or if a high degree of precision is unnecessary for a specific therapeutic regime.

In another aspect of the present invention, gravity is used to deliver medicine from the barrel 10 to the patient. In FIG. 11, the syringe barrel is shown in a vertical position with the plunger 16 near the end of the barrel 11 opposite the fluid port 14. In FIG. 11, it is assumed that medicine has been introduced into the barrel 10. Assuming the barrel 10 is maintained in the vertical position, gravity will act upon the fluid and plunger 16 to pull the plunger 16 towards the fluid port 14, as seen in FIG. 12. This reduces the volume of the bore 11 and delivers medicine through the fluid port 14. It may thus

be appreciated that gravity may be used to deliver medicine through a syringe barrel, without the use of any plunger stick whatsoever.

With reference to FIG. 7, another embodiment of the present invention includes a locking mechanism between a plunger and a pump mechanism. In FIG. 7, reference numerals corresponding to those depicted in FIGS. 1 - 6 have "100" added to them, so that, for example, syringe barrel 110 in FIG. 7 corresponds to syringe barrel 10 in FIG. 1, etc. A slidable plunger 116 is disposed within the syringe barrel 110. A pumping mechanism 140 may be used to drive the plunger 116 through the plunger barrel 110 to deliver medicine through a fluid port 114. A fill port 115 may also be present at the proximal end of the barrel 110.

A pump plunger stick 142, driven by a motor 144, mates with the plunger 116 in a locking relationship. The proximal end of the pump plunger stick 142 has a proximal locking end 160 that mates with a receptacle 121 of the plunger 116. The locking means may be of the twist snap type. Thus, the when the end 160 of the stick 142 is inserted in the receptacle 121 and rotated, camming surfaces 162 bind in the receptacle and the connection is secured. The connection may be broken by applying a counter-rotational force to the stick 142, and retracting the stick 142. While a twist snap connection is one preferred embodiment of the present invention, it should be appreciated that components forming other simple, detachable locking connections may also be used with good results, and are alternative designs.

The reliable connection formed between the stick 142 and the plunger 116 prevents inadvertent motion of the plunger 116 relative to the barrel 110, and allows the plunger position to be positively controlled by the stick 142. This prevents the plunger from creeping towards the

fluid port 114 (or in the opposite direction), and maintains the integrity of the fluid within the barrel 110.

In operation, the syringe barrel 110 may be filled with medicine as with the previously described embodiment. A detachable plunger stick (not shown), similar to the stick 30, may have a mating end to mate with plunger receptacle 121, and be used to fill the syringe barrel 110. To introduce the medicine into a patient, the syringe barrel 116 is attached to the pumping mechanism 140, and the pump plunger stick 142 is securely fastened to the plunger 116 using the locking means 160. Afterwards, the motor 144 may be activated to drive the pump plunger stick 142, hence the plunger 116, to release medicine through the fluid flow port 114. After the medicine has been introduced into the patient, the pump plunger stick may be unlocked from the syringe barrel 116, and the syringe barrel may be removed from the pumping mechanism 140. Another syringe barrel may be engaged with the pumping mechanism 140 to again release medicine, when desired.

In operation of the gravity embodiment as shown in FIGS. 11 and 12, the syringe barrel 10 is filled with medicine with any method described above. The fluid port is placed in fluid communication with a patient. The syringe is placed in the vertical position of FIG. 11. Gravity will thereafter act upon the plunger 16, drawing it to the end of the syringe barrel having the fluid port 14 (see FIG. 12), and simultaneously expelling medicine therefrom.

The barrel 10 or plunger 16 may be provided with a latch to prevent the plunger 16 from moving in relation to the barrel until such movement is desired. This would allow the syringe barrel 10 to be maintained in a vertical position before it is descried to deliver

medicine. Such a latch would also allow a filled syringe barrel 10 to be safely transported and stored without possible inadvertent plunger 16 movement

The present invention may include a removable protective barrier, as may be seen by reference to FIGS. 8 and 9 where reference numerals corresponding to those of FIGS. 1 - 6 have "200" added to them, so that syringe barrel 210 of FIG. 8 corresponds to syringe barrel 10 of FIG. 1, etc. A membrane barrier 270 is attached to the distal end of the syringe barrel 210, so that the distal end of the syringe barrel is completely covered. The proximal end of the syringe barrel has a fluid port 214, and optionally a fill port as described above. The membrane 270 maintains the medicine in a sterile condition until the medicine is ready to be used, and may be attached before or after the medicine is introduced into the barrel 210. The medicine could be introduced at a manufacturing plant, by a pharmacist, or in any other manner where an appreciable amount of time will elapse between the filling and application of a syringe.

The membrane 270 may be attached by any suitable method; a preferred method is through the use of adhesives. Adhesives placed on the membrane 270 may be used to stick the membrane 270 onto the syringe barrel 210. As may be seen with reference to FIG. 9, the membrane 270 then may be peeled off the syringe immediately before use, allowing access to the plunger 216 so that it may be driven towards the proximal fluid port 214 to release medicine. While the membrane 270 may have application with any medicinal syringe, it is particularly useful with syringes having a plunger without an integral plunger stick, as described above. This is because the membrane may then simply cover the

distal end of the barrel 210, without having to accommodate a projecting stick, which would require some means to seal such a stick and the barrier.

The membrane may, but need not, include a tab 270 that extends beyond the barrel 210. This tab 270 allows the membrane to be easily removed from the barrel 210, as the tab may be grasped and lifted from the barrel 210, thereby removing the entire membrane 270.

An alternative attachment method is depicted in FIG. 10. A membrane 274 is fitted over the barrel 210, and held in place by cap 276 that mates with the barrel 210. The cap 276 preferably exerts at least some compressive force on the membrane 274 to maintain the membrane 274 and barrel 210 in sealing engagement. This may be accomplished by threads 278 on the cap that mate with corresponding threads 211 on the syringe body. The threads 211 are of only present on the barrel if a threaded cap 274 is used. A threaded engagement allows the cap to be securely attached to the barrel, and yet be easily removed when desired. However, other attachment means, such as a bayonet engagement, may be used instead.

As depicted in FIG. 10, the cap has an annular above the top of the membrane 274. This is particularly useful if a breathable membrane 274 is used, so that the gas inside of the barrel 210 can communicate with the atmosphere. A cap having a solid top surface could be used if it is not desired to allow gaseous communication across the membrane 274.

The membrane 270 may be made of a material to provide a full hermetic seal, that is, it may be impervious to any gaseous or fluid transport. Or, the membrane 270 may form a partial hermetic seal in that it may allow gaseous transport, but prevent the passage of micro-organisms. This aspect of the inventions allows a pharmacist to aseptically fill the container within a sealed system

that maintains the sterility of the syringe. A number of materials having the proper porosity will accomplish such selectively; tyvek is one such material. This use of a partial hermetic seal insures sterility, and allows air to be expelled from the distal end of the barrel 210, such as by manipulating the position of the barrel so that medicine is forced into contact with the membrane 270.

In operation, medicine is introduced into each syringe barrel 210, as described above in connection with the previous embodiments. The membrane 270 is applied to the distal end of the syringe barrel 210, to seal the syringe barrel and prevent micro-organisms from contaminating the medicine. It should be appreciated that the membrane may be attached before or after the medicine is introduced. The syringe barrel 210 may then be stored for as long a period of time as is desired. When the medicine contained within the barrel 210 is ready to be introduced into a patient, the membrane 270 is removed, such as by lifting the membrane tab 272. The syringe may be then be engaged with a pumping mechanism, or a simple pump stick, and the plunger may be activated. If the gravity feed method as described above is used, the membrane 270 does not have to be removed prior to use provided that the membrane is breathable, and no pump stick or equivalent is engaged to the plunger.

It may thus be appreciated that the present invention provides a syringe having a plunger that does not require an integrated plunger stick. Instead, depending upon the embodiment of the invention, the stick is present in a pumping mechanism, or else no stick at all is required. The invention further provides for aseptic packaging which is particularly well suited for the disclosed syringe.

CLAIMS

What is claimed is:

1. A syringe system for delivery of medication, comprising:

a syringe barrel defining a bore therewithin, the barrel having a proximal end and an open distal end, the proximal end having a fluid flow port; and

a plunger slidably disposed within the bore and forming a close tolerance therewith, the plunger not having an integral plunger stick.

2. The syringe system of claim 1, further comprising a plunger stick for sliding the plunger, the plunger stick being detachably attachable to the plunger; and the plunger stick extending distally from the plunger when attached thereto.

3. The syringe system of claim 2, wherein the plunger stick has a threaded proximal end, the plunger has a threaded receptacle, and the plunger stick is detachably attachable by threading the plunger stick proximal end into the plunger receptacle.

4. The syringe system of claim 1, further comprising a pumping mechanism, the pumping mechanism being engagable with the distal end of the syringe barrel, the pumping mechanism having a pump plunger means for engaging and sliding the plunger, and a pump motor for sliding the pump plunger means at a controlled rate.

5. The syringe system of claim 4, wherein the pump plunger means is a plunger stick.

6. The syringe system of claim 5, wherein the pump plunger stick positively engages the plunger.

7. The syringe system of claim 6, wherein the pump plunger stick has a locking cam, the plunger has a cam receptacle that receives the locking cam and allows for cam rotation, and the positive engagement between the pump plunger stick and the plunger is made by inserting the locking cam into the plunger cam receptacle and rotating the cam.

8. The syringe system of claim 7, wherein the pump plunger stick may be unlocked from the plunger by counter-rotating the pump plunger stick when it is inserted within the plunger.

9. The syringe system of claim 1, further comprising a membrane, the membrane being attached to the distal end of the syringe barrel to cover the same, the membrane being of a material that prevents micro-organism transport therethrough.

10. The syringe system of claim 9, wherein the membrane is detachably attachable by an adhesive on the membrane that adheres to the syringe barrel.

11. The syringe system of claim 9, wherein the membrane is gas impermeable.

12. The syringe system of claim 9, wherein the membrane is gas permeable.

13. The syringe system of claim 10, wherein the membrane is made of tyvek.

14. The syringe system of claim 9, wherein the membrane seats within a cap, the cap being attachable to the distal end of the syringe barrel.

15. The syringe system of claim 9, wherein the membrane includes a tab extending beyond the syringe barrel when the membrane is attached to the syringe barrel, whereby the membrane may be detached from the syringe barrel by pulling the tab.

16. A syringe pump for delivery of medication, comprising: a housing; a motor contained at least partially within the housing; pump means contained at least partially within the housing, the pump means being drivable by the motor; wherein the housing is adapted to receive a syringe barrel having a plunger so that the pump means can drive the plunger through the barrel.

17. The syringe pump of claim 16, wherein the pump means is a pump stick.

18. The syringe pump of claim 17, wherein the pump stick is adapted to positively lock with the plunger.

19. The syringe pump of claim 18, wherein the positive locking is enabled by a cam on the stick which is adapted to mate with a cam receptacle on the plunger.

20. A method of administering medication, comprising:

(a) filling a syringe barrel having a fluid port and a plunger with an amount of medicine;

(b) engaging the syringe barrel with a pumping mechanism having a pump plunger means for advancing the plunger to release medicine through the fluid port;

(c) placing the fluid port in communication with a patient; and

(d) advancing the plunger through the syringe barrel.

21. The method of claim 20, wherein the pump plunger means is a plunger stick.

22. The method of claim 21, wherein the step of filling the syringe barrel includes attaching a detachable plunger stick to the plunger, placing the fluid flow port in communication with a medicine reservoir, and advancing the plunger stick towards the fluid flow port.

23. The method of claim 21, wherein the step of engaging the syringe barrel with the pumping mechanism provides positive locking between the plunger and the pump plunger stick.

24. The method of claim 21, further comprising the step of placing a membrane over the syringe barrel opposite the fluid, the membrane preventing micro-organism transport therethrough.

25. The method of claim 24, wherein the membrane is gas permeable.

26. The method of claim 24, wherein the membrane is gas impermeable.

27. The method of claim 24, further comprising the step of detaching the membrane from the syringe barrel, this step being performed before advancing the plunger through the syringe barrel.

28. The method of claim 24, wherein the step of detaching the membrane includes pulling a tab on the membrane.

29. A method of operating a syringe pump for delivery of medication, comprising:

attaching a syringe barrel onto the pump;

engaging a pump plunger means located at least partially within the pump with a plunger located at least partially within the barrel;

driving the pump plunger means and thereby driving the plunger by activating a motor engaged with the pump plunger means the motor being contained at least partially within the syringe pump.

30. The method of claim 29, wherein the pump plunger means is a plunger stick.

31. The method of claim 30, wherein the step of engaging the pump plunger stick to the plunger is positively and lockingly made.

32. The method of claim 31, wherein the step of engaging the pump plunger stick to the plunger is positively and lockingly made by a cam on the stick fitting into a cam receptacle on the plunger.

33. A method of administering medication, comprising:

(a) filling a syringe barrel having a fluid port and a plunger with an amount of medicine;

(b) placing the fluid port in communication with a patient; and

(c) placing the syringe barrel in a vertical position, whereby gravity advances through the plunger through the syringe barrel to force medicine through the fill port.

34. The method of claim 33, further comprising the step of placing a membrane over the syringe barrel opposite the fluid flow port, the membrane being gas-permeable and micro-organism impermeable.

35. The method of claim 33, wherein the filling step utilizes a fill port separate from the fluid port.

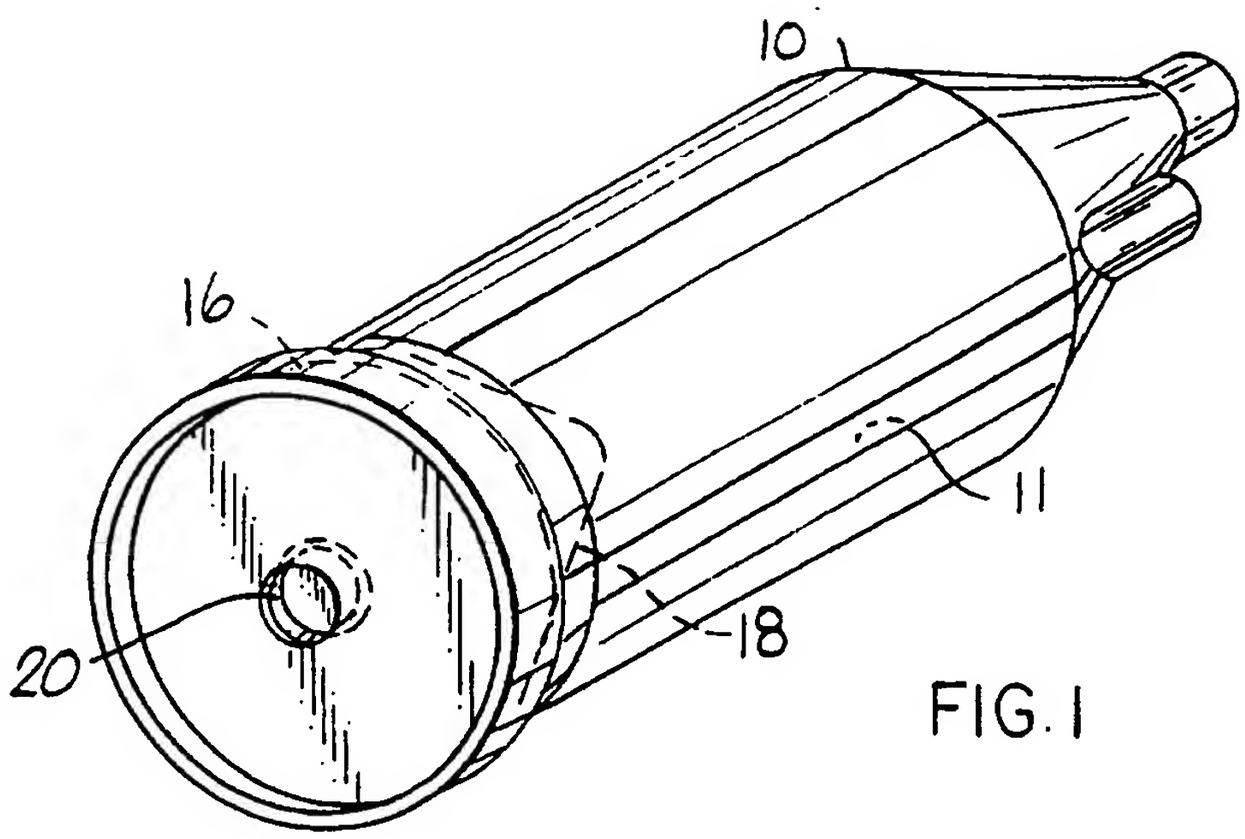

FIG. 1

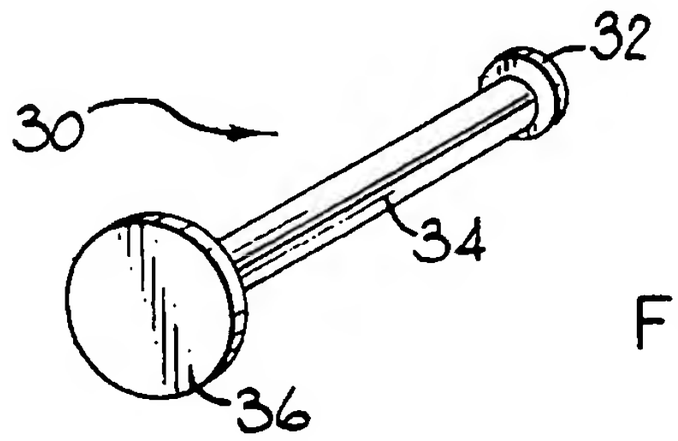

FIG. 2

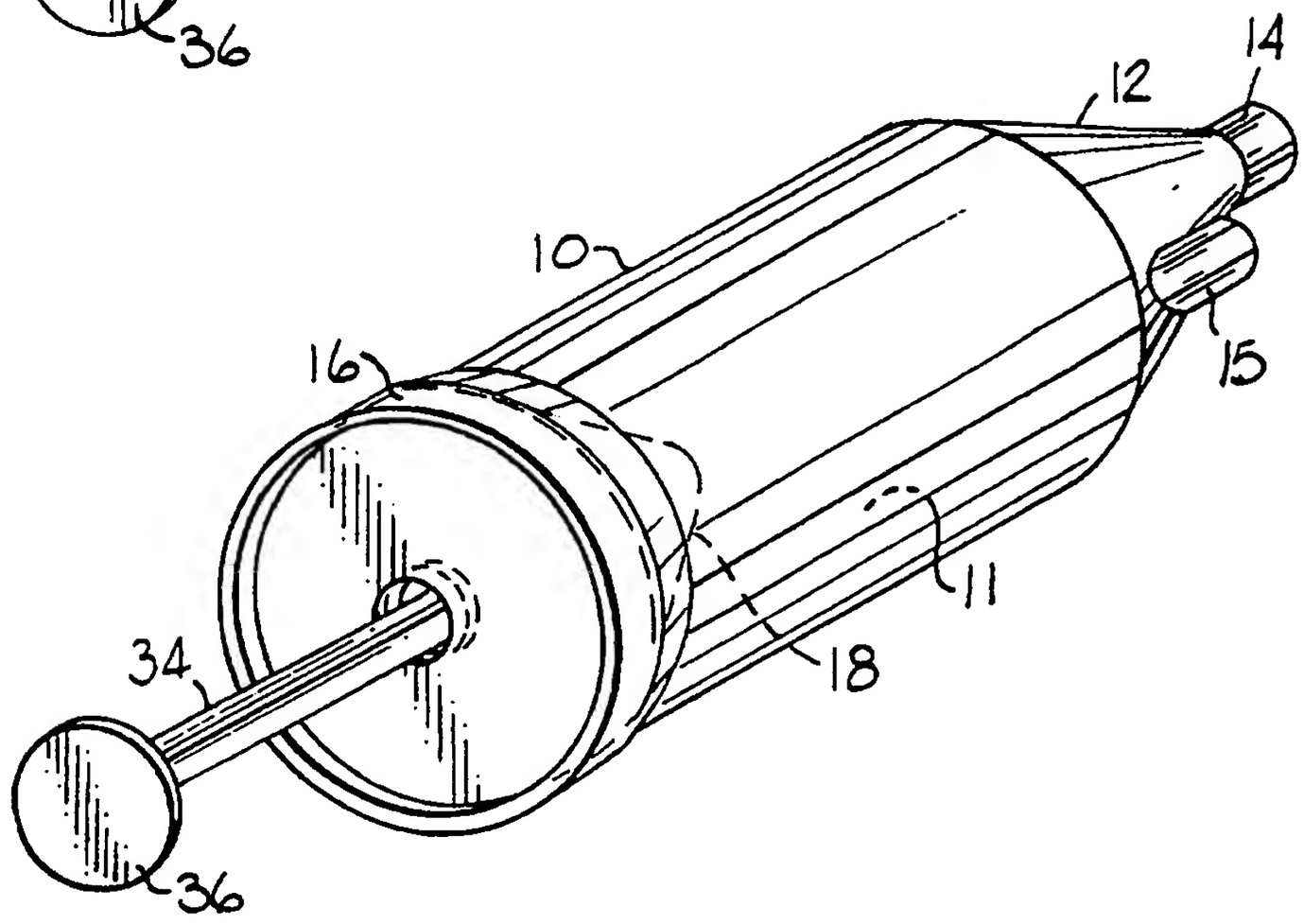

FIG. 3

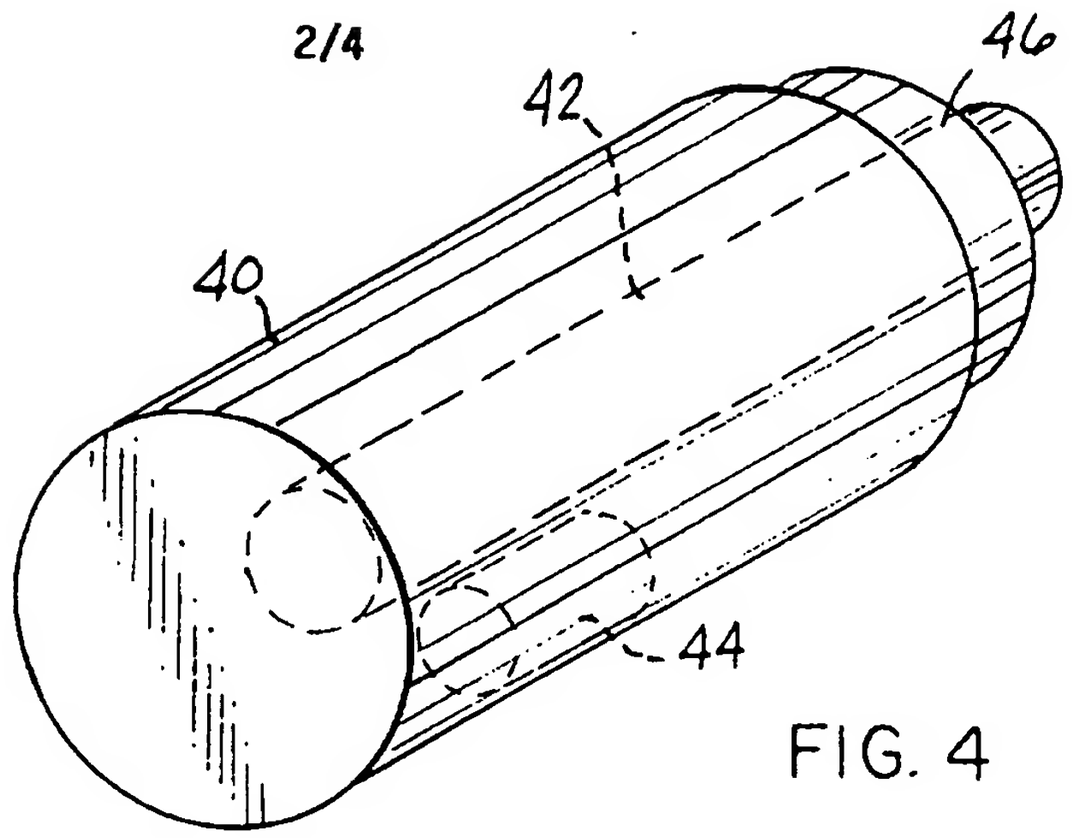

FIG. 4

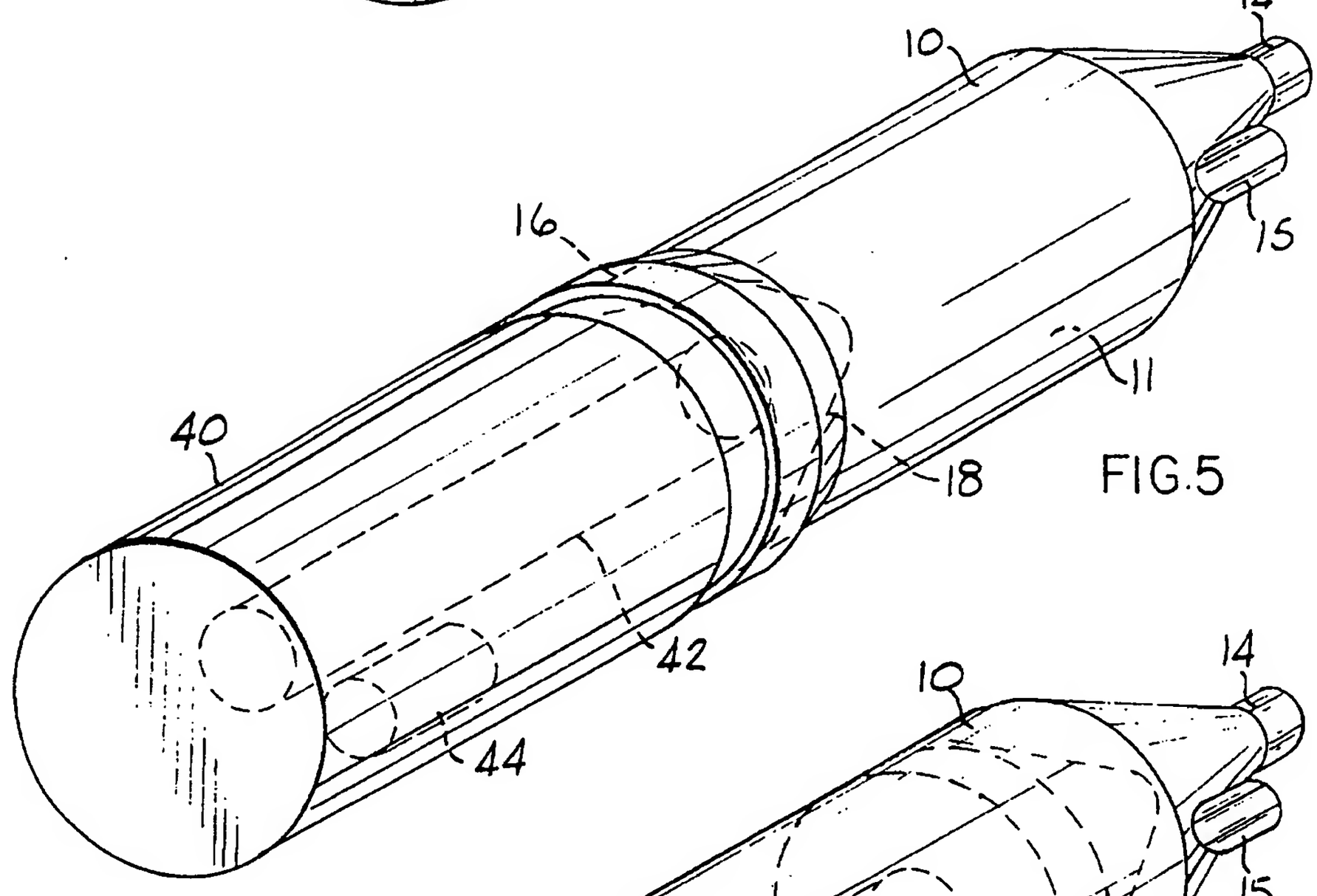

FIG.5

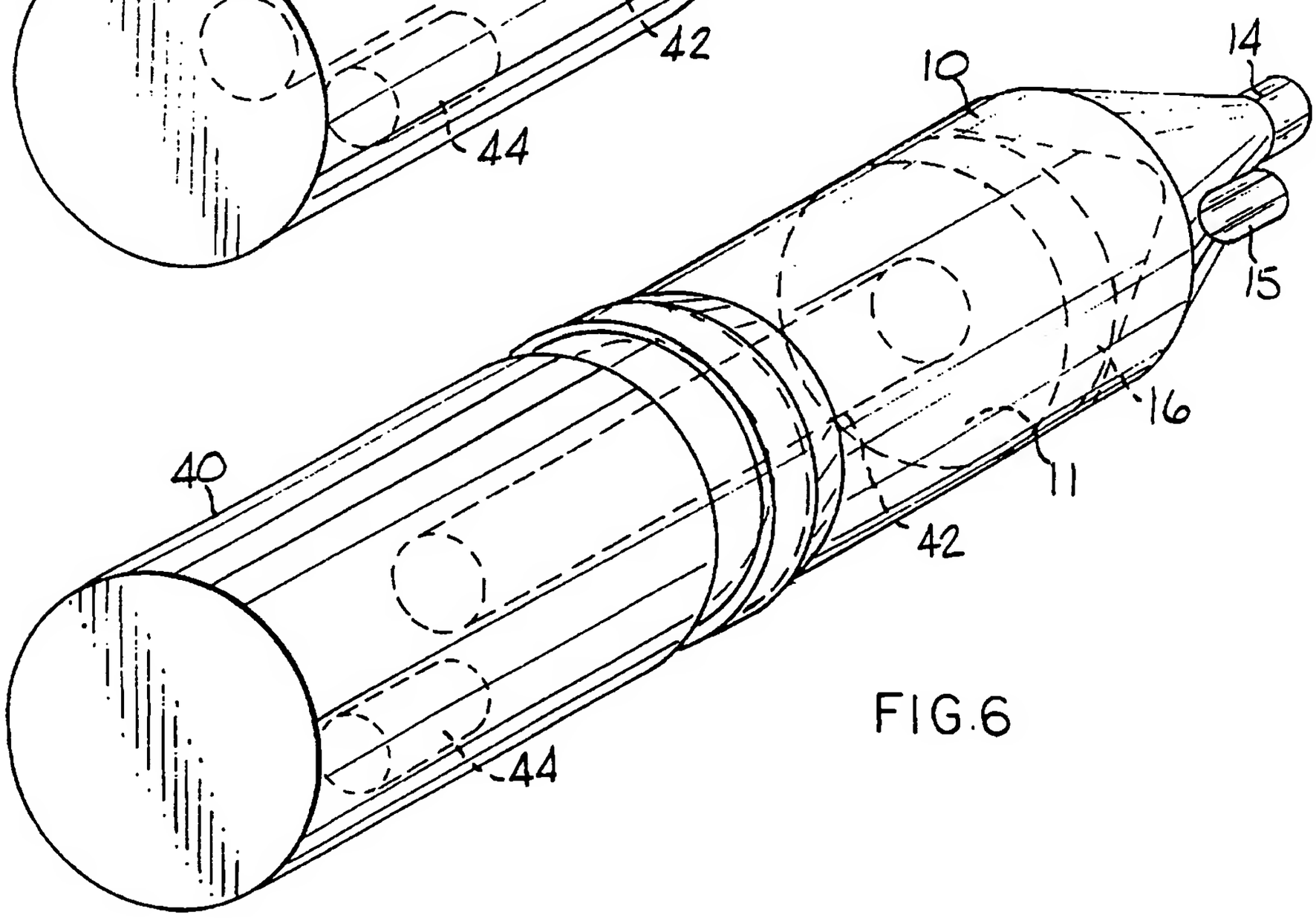

FIG.6

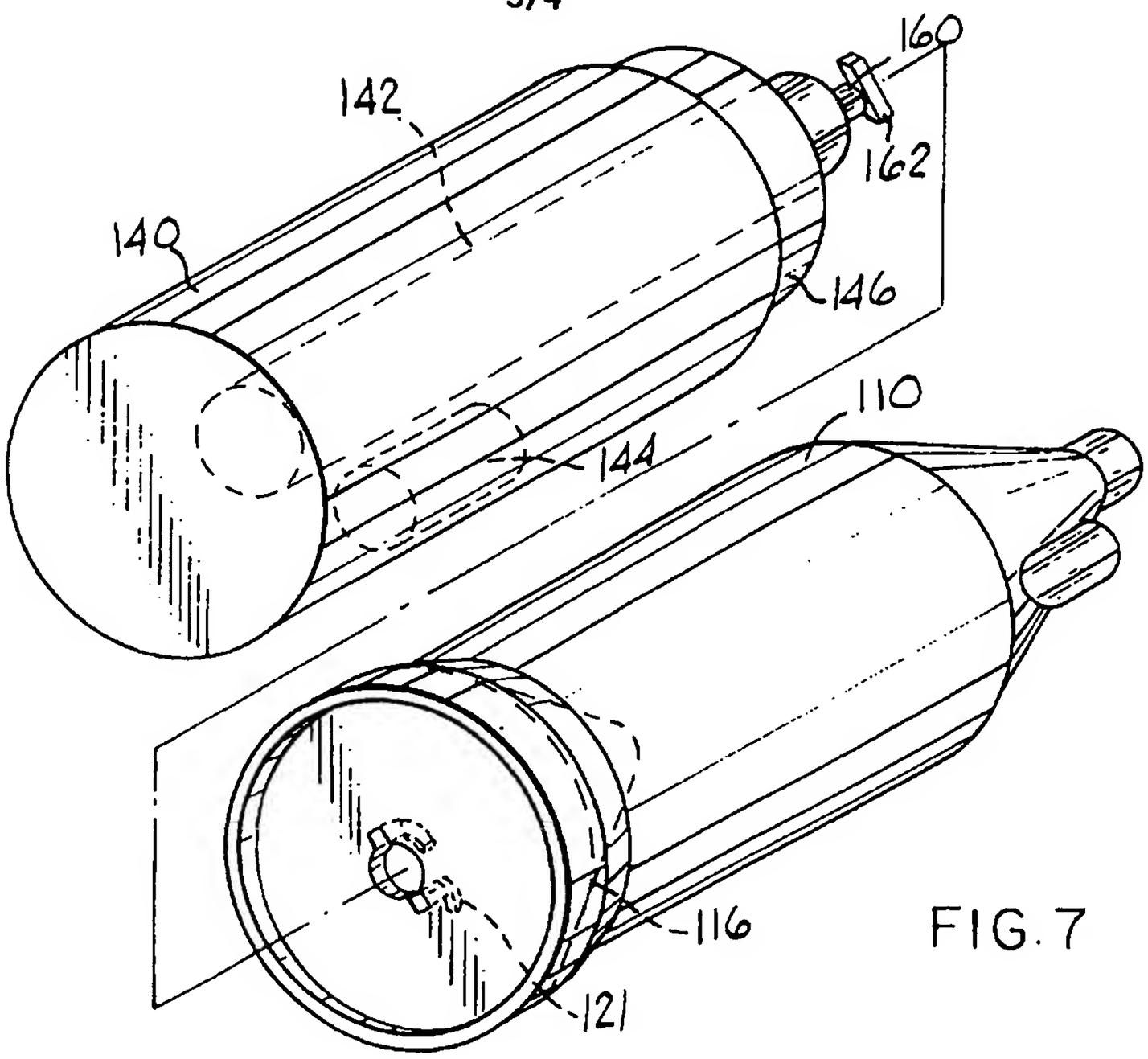

FIG. 7

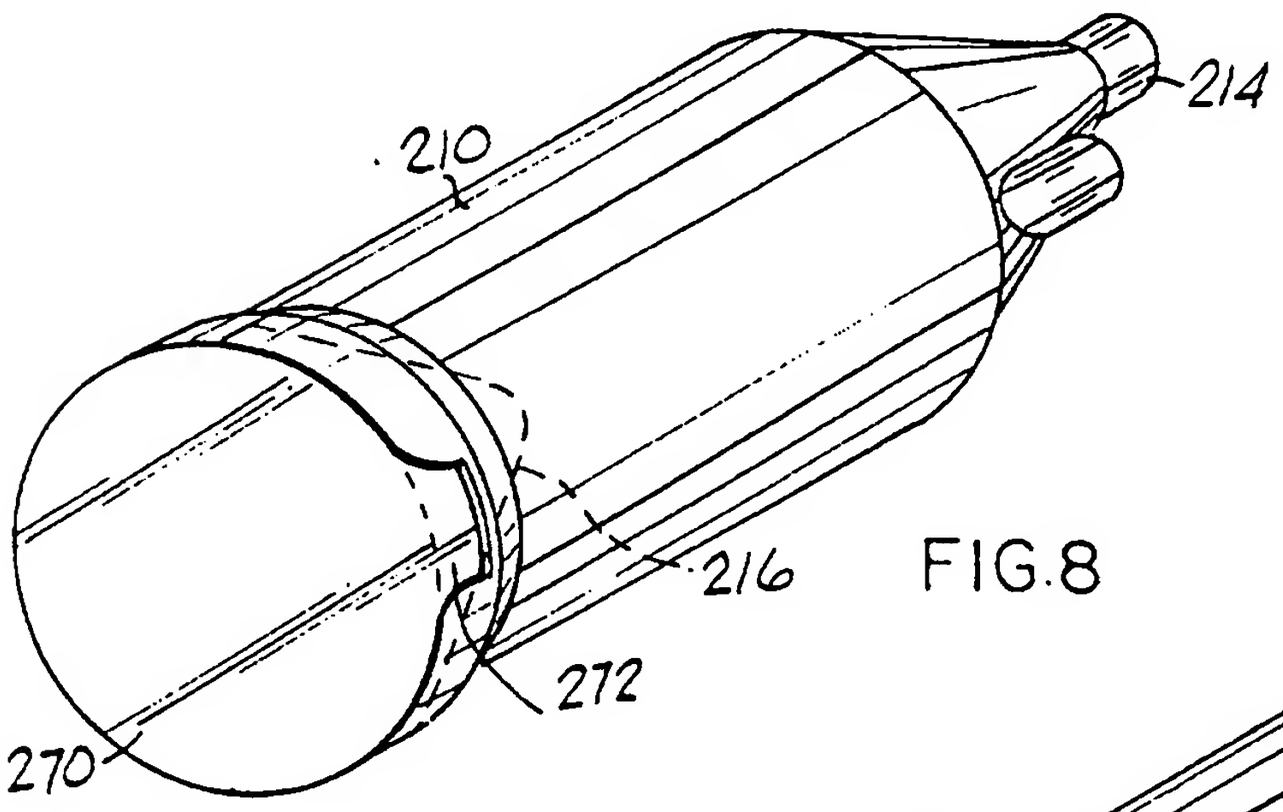

FIG. 8

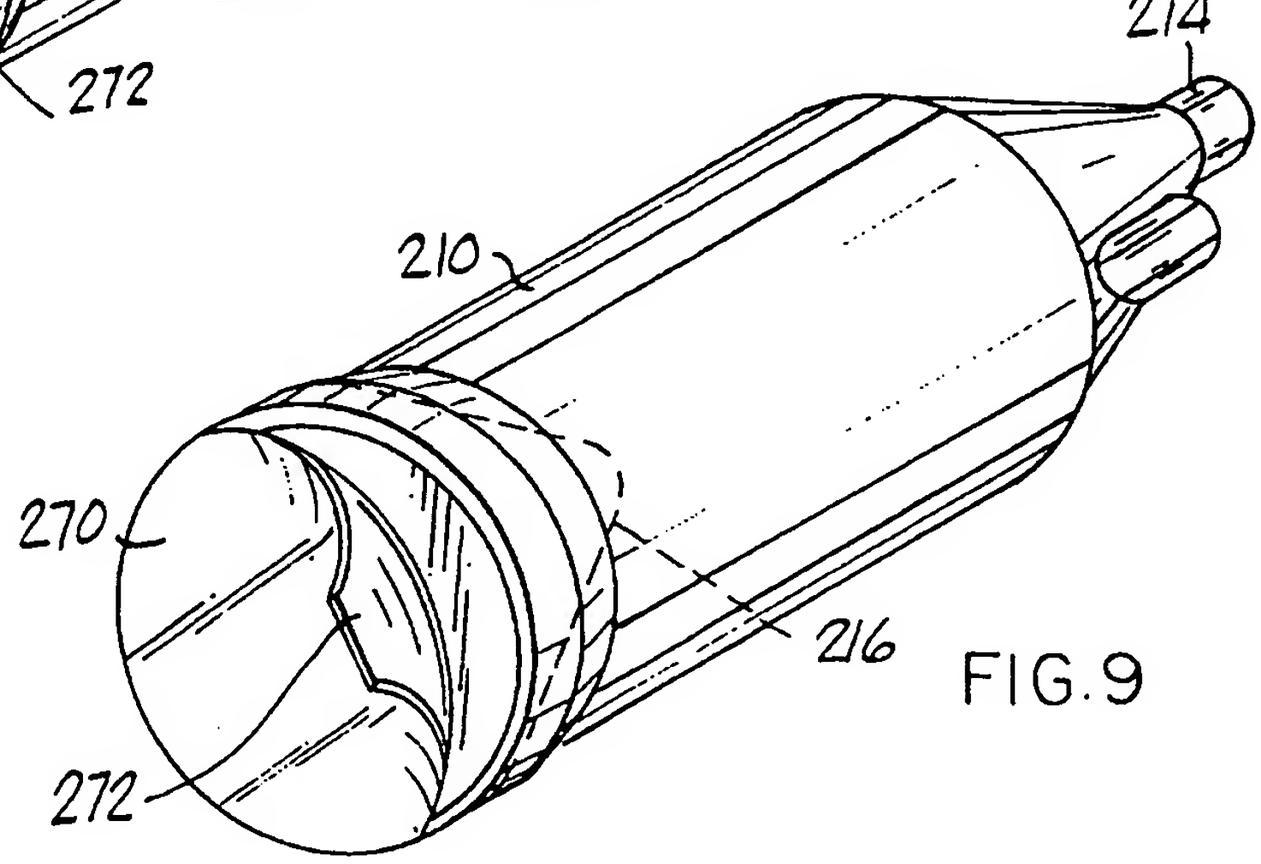

FIG. 9

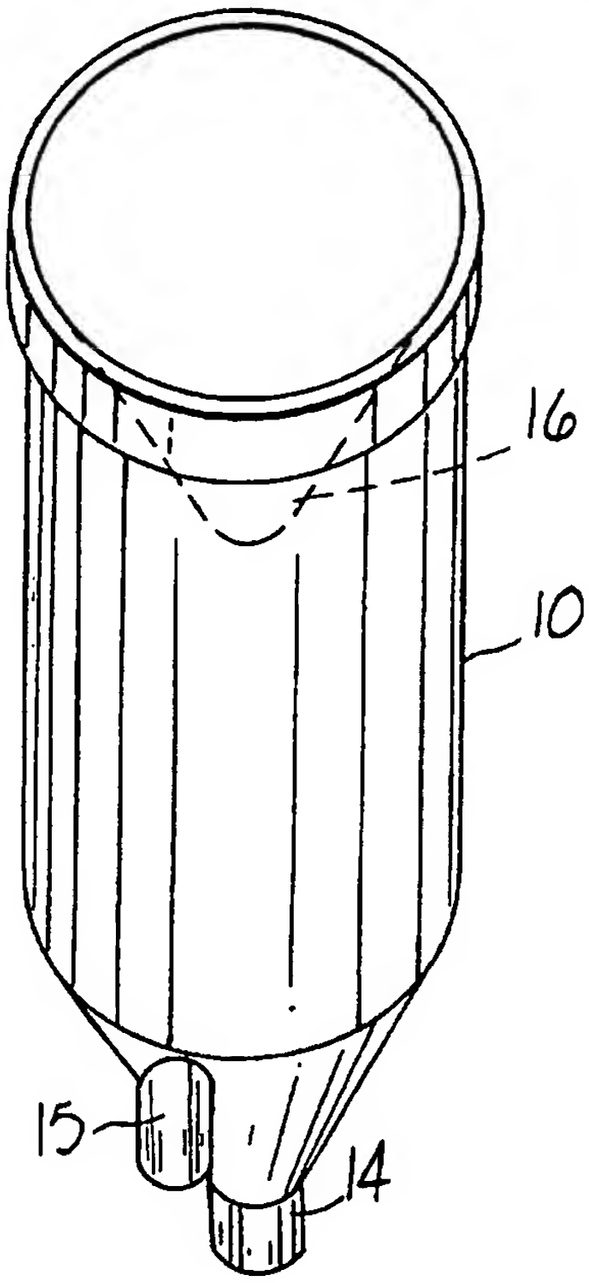

FIG.11

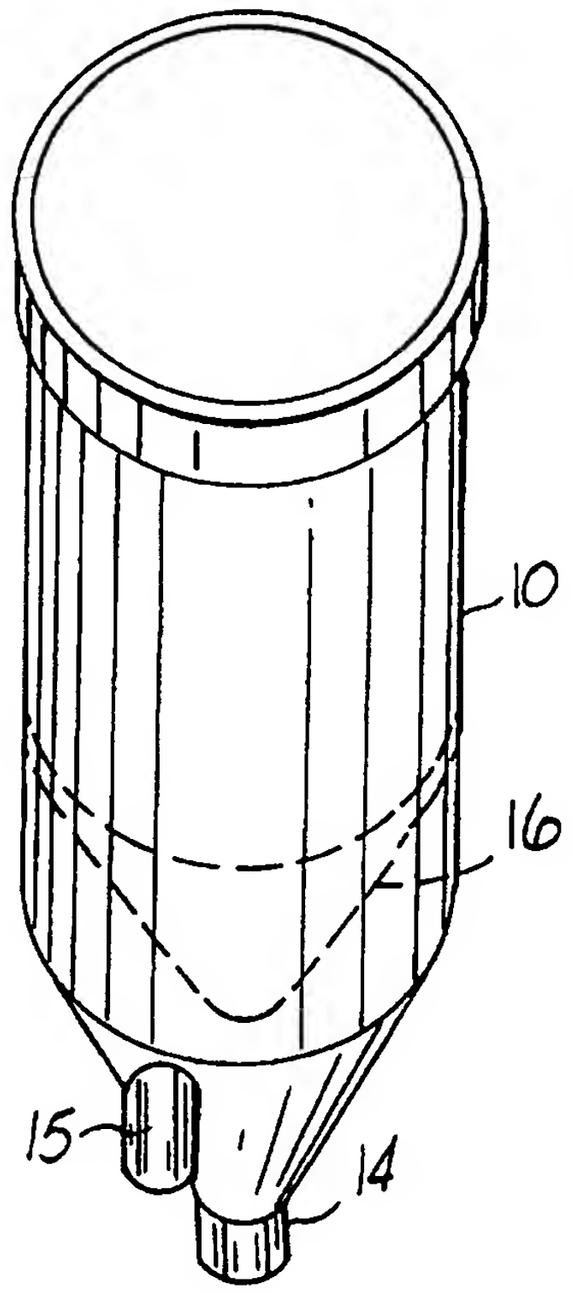

FIG.12

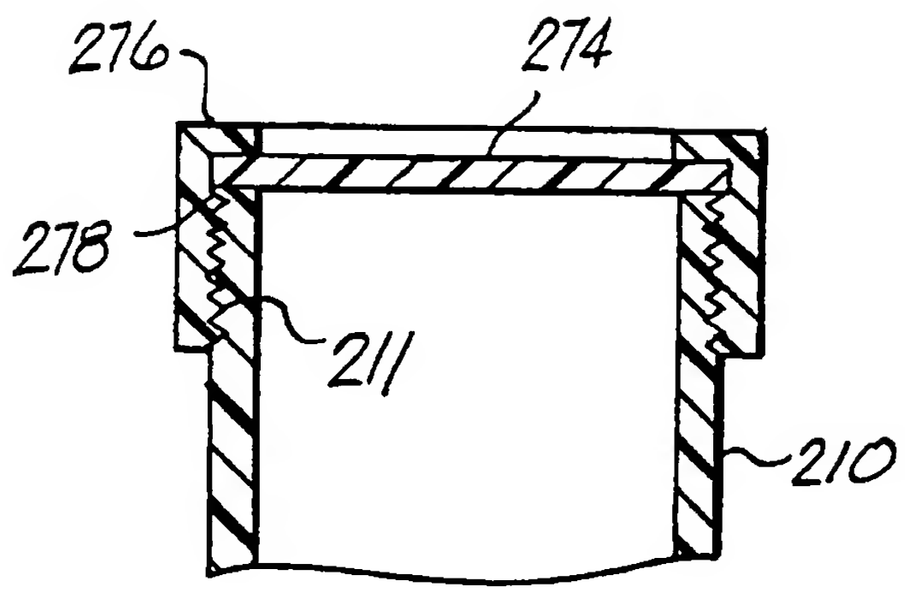

FIG.10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/12881

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M1/00
US CL :604/151

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/80, 131, 151, 154,155, 181, 403

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,966,585 A (GANGEMI) 30 October 1990, entire reference.	1-3, 20-23 --- 4-19, 29-32
X --- Y	US 5,401,253 A (REYNOLDS) 28 March 1995, entire reference.	33 --- 35
Y	US 5,383,858 A (REILLY et al) 24 Janury 1995, entire reference.	4-8, 16-19, 29-32
Y	US 1,765,794 A (HIRTH) 24 June 1930, entire reference.	9-13, 15
Y	US 5,061,263 A (YAMAZAKI et al) 29 OCTOBER1991, entire reference.	14

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 09 OCTOBER 1997	Date of mailing of the international search report 10 NOV 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LUKE YEH Telephone No. (703) 308-3384

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/12881

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,084,021 A (BALDWIN) 28 January 1992, entire reference.	35
A	US 3,993,065 A (SZABO et al) 23 November 1976, entire reference.	1-35
A	US 5,279,608 A (CHERIF CHEIKH) 18 January 1994, entire reference.	1-35